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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,637	03/15/2002	Gerardo M. Castillo	PROTEO.P16CI	4148

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,637	CASTILLO ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2005 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed January 13, 2005, and amendment and response to the Final Office Action (July 13, 2004), filed January 13, 2005 wherein claim 18 is cancelled; claims 12-13 have been amended. Claims 1-8 and 16 are cancelled previously.

Currently, claims 9-15 and 17 are pending in this application and under examination on the merits.

Applicant's amendment filed on January 13, 2005 with respect to the rejection of claims 12-13 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations, i.e., " pharmaceutical acceptable analogs and derivatives" of record stated in the Office Action dated July 13, 2004 have been fully considered and found persuasive to remove the rejection since the recitation " pharmaceutical acceptable analogs and derivatives" has been deleted from the claims. Therefore, the said rejection is withdrawn.

Applicant's amendment filed on January 13, 2005 that cancels claim 18 with respect to the rejection of claim 18 made under 35 U.S.C. 103(a) as being unpatentable over Kuznicki et al. (5,681,569) or JP 10245342 for reasons of record stated in the Office Action dated July 13, 2004 have been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681,569) for reasons of record stated in the Office Action dated July 13, 2004.

Kuznicki et al. discloses a composition comprising 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, col.2, lines12-14; Example I, II, and III at col.10, and claims 1 and 5-6. Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (10-

100mg/kg of body weight of the subject), is disclosed in the Example I and III (see col. 10 lines 1-41) as shown in the calculation below:

Example III discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example I, the effective amount of catechins (or flavanols)

= 835g X 0.097% (see col.10 line 15 in particular) = 0.8099 g = 809.9 mg

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

= 835g X 0.35/100 X 29/100 = 0.8475 g = 847.5 mg.

Since a standard person weight is 70 kg, the range of effective amounts of catechins is 10 mg/kg X 70 kg =700 mg to 1000 mg/kg X 70 kg = 70,000 mg.

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to

significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

Thus, Kuznicki's composition inherently treat amyloid in a mammal. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Thus, Kuznicki et al. anticipates claims 9-15 and 17.

Response to Argument

Applicant's arguments filed January 13, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Again, Applicant's arguments that "[t]he disclosures of Kuznicki are not directed to therapeutics for diseases of any sort" and that "Kuznicki does NOT address any kind of general cognitive improvement with his formulation, but rather a very specific "increased cognitive performance after heat dehydration, but rather a very specific "increased cognitive performance after heat dehydration", are not persuasive, since the instant claims are directed to a pharmaceutical composition not a method of treating amyloid disease in a mammal. It has been well settled that recitation of an inherent

property of a composition, e.g., "treating amyloid" in claims herein, will not further limit claims drawn to a composition so long as the prior art teaches the composition comprising the same ingredients in the **same** amount, e.g., the same amount of catechins.

Therefore, Kuznicki's composition is deemed to have the inherent property for treating amyloid in a mammal when administering the Kuznicki's composition to a mammal. Moreover, even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicant further assets that "claim 17 is especially distinguished over the cited art by substituting the words "consisting of" for the word "comprising" in original claim 1, Thus Claim 17 can not be read upon the formulations of Kuznicki because those formulations have ingredients other than catechins and excipients and the like. Contrary to Applicant's assertion, claim 17 can not be read upon the formulations of Kuznicki, since claim 17 herein recites:

"A pharmaceutical composition consisting of a therapeutically effective amount of a catechin and a pharmaceutically acceptable carrier, diluent, or excipient, the therapeutic amount of the catechin selected for efficacy in treating amyloid, alpha-synuclein or NAC fibrillogenesis in a mammalian subject."

Note that the specific composition of Kuznicki et al. in Example I consists of fruit juice, green tea solids, flavoring, sodium citrate, asorbic acid, aspartame, glucose, and water (see Example 1 at col.9-10). Thus, "fruit juice, flavoring, sodium citrate, asorbic

acid, aspartame, glucose, and water" are deemed to read on a pharmaceutically acceptable carrier, diluent, or excipient.

Thus, Kuznicki et al. anticipates claims 9-15 and 17.

Claims 9, 12-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 for reasons of record stated in the Office Action dated July 13, 2004.

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by β–amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts (doses) of diminishing the toxicity of β–amyloid protein (see particularly page 1, the 2nd paragraph; claims 1-3 at page 1; page 2 [0001], [0002]), and a pharmaceutical carrier (i.e., water). See also page 7 [0028]; page 8 [0029]. JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, JP 10245342 anticipates claims 9, 12-15, and 17.

Response to Argument

Applicant's arguments filed January 13, 2005 and the declaration of Alan Snow under 37 CFR 1.132 filed September 11, 2003 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not

deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant's arguments that "Specifically, there is no way to tell with any certainty that a formulation proposed by Mitsui Norin to reduce amyloid toxicity would also and at the same time necessarily have the effect of inhibiting or reversing amyloid fibrillogenesis, much less alpha-synuclein or NAC tibrillogenesis" are not convincing for the following reasons.

Again, Applicant is reminded that the instant claims are directed to a pharmaceutical composition, not a method of treating amyloid disease in a mammal, nor methods of inhibiting or reversing amyloid fibrillogenesis, much less alpha-synuclein or NAC tibrillogenesis. So long as JP 10245342 discloses the composition comprising the same ingredients in the effective amount of catechins for diminishing the toxicity in nerve cells caused by β–amyloid protein, it meets the claimed limitations. Thus, the prior art composition is deemed to have the inherent property for treating amyloid in a mammal. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Further, Applicant assertion in the declaration under 37 CFR 1.132 using the reference by Wang that "there are no necessary inferences available as teachings to be applied to Aβ fibrillogenesis from the cited studies pertaining to neuronal cell death, because in at least some of the reported studies, the causes of the cell death do not involve any effect on Aβ sbrillogenesis" and "There is thus no implication available to

serve as a teaching that inhibition of nerve cell death or nerve cell toxicity by Aβ inherently leads to inhibition of Aβ fibril formation, deposition, accumulation and/or persistence" have been fully considered but not found convincing.

First, as indicated above, the instant claims are not a method claims. Second, even if the method of treatment were claimed herein, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the claimed method steps are already known even though applicant has proposed or claimed the mechanism. Third, the declaration merely presents statements or inferences or inconclusive mechanistic studies, but fails to set forth any factual evidences. Therefore, the declaration of Snow is not persuasive to rebut the prima facie case herein.

Regarding claim 17, a cup of green teas disclosed by JP 10245342 (see [0005]) is deemed to clearly read on claim 17.

Thus, JP 10245342 anticipates claims 9, 12-15, and 17.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9-11 of the copending Application No. 10/762,444.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a drug product for treating amyloidosis in a mammal comprising a composition a compound of Formula E which is epicatechin (see Fig. 1B herein) and a pharmaceutically acceptable excipient.

The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin and a pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/762,444.

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of the copending Application No. 10/610,349.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amyloidosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas.

The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin present in green teas and a pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,349.

Claims 9-15 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of the copending Application No. 10/610,346.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amyloidosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas.

The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin present in green teas and a pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,346.

Above obviousness-type double patenting rejections are are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
April 19, 2005